

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

UNITED STATES OF AMERICA,

Plaintiff,

CENTER FOR ENVIRONMENTAL HEALTH,
PUBLIC EMPLOYEES FOR ENVIRONMENTAL
RESPONSIBILITY, and JAY DE LA ROSA,

Intervenor-Plaintiffs.

v.

INHANCE TECHNOLOGIES LLC,

Defendant.

Civil Action No. 5:22-cv-05055-JFM

DEFENDANT'S SUBMISSION IN RESPONSE TO DECEMBER 4 ORDER

Catherine E. Stetson*
Susan M. Cook*
Adam M. Kushner*
HOGAN LOVELLS US LLP
555 Thirteenth Street, NW
Washington, D.C. 20004
Tel: (202) 637-5600
cate.stetson@hoganlovells.com

Virginia Gibson (PA Bar No. 32520)
HOGAN LOVELLS US LLP
1735 Market St., Floor 23
Philadelphia, PA 19103
Phone: (267) 675-4635
Fax: (267) 675-4601
virginia.gibson@hoganlovells.com

J. Tom Boer*
HOGAN LOVELLS US LLP
4 Embarcadero Center, Suite 3500
San Francisco, CA 94111
Tel: (415) 274-2300
tom.boer@hoganlovells.com

Dated: December 11, 2023

Counsel for Inhance Technologies LLC

*admitted pro hac vice

INTRODUCTION

The posture of this case has changed, but the legal principles that govern its outcome remain the same. The Government—later joined by plaintiff-intervenors PEER and CEH—sued Inhance under the Toxic Substances Control Act (TSCA) on the theory that Inhance failed to submit a Significant New Use Notice (SNUN) relating to its decades-old fluorination process after the agency finalized a Significant New Use Rule (SNUR) in July 2020. As Inhance explained in its motions to dismiss the Government’s and Intervenors’ Complaints, the SNUR does not apply to Inhance’s 40-year-old fluorination process, which is not a “new use” within the meaning of either the statute or regulation. And because any long-chain PFAS generated unintentionally during Inhance’s fluorination process constitutes an impurity exempt from the SNUR’s mandate—rather than an actionable byproduct—the company’s fluorination process would not be governed by the SNUR anyway. For these reasons, Inhance is not subject to the statutory or regulatory requirements that form the basis for claims under 15 U.S.C. § 2616.

The only change brought about by recent events is that Plaintiffs’ claims are now also moot. On December 1, EPA issued two Unilateral Orders, the effect of which is to shut down Inhance’s decades-old fluorination process.¹ Inhance has now filed a petition for review with the United States Court of Appeals for the Fifth Circuit, which has exclusive jurisdiction to assess the lawfulness of the Unilateral Orders. 15 U.S.C. § 2618(a)(1)(A). Because the Unilateral Orders, if permitted to go into effect, would almost immediately drive the company into bankruptcy, Inhance

¹ At the same time, EPA exercised its authority under TSCA § 5(c), 15 U.S.C. § 2604(c), to unilaterally extend the review period for Inhance’s SNUNs by 90 days, until February 28, 2024. This extension was a necessary prelude to EPA’s issuance of the Unilateral Orders because the agency was not authorized to issue orders unless there was at least 45 days remaining before the expiration of the review. 15 U.S.C. § 2604(e)(B). However, because the Unilateral Orders are final agency action, and already subject to a petition filed in the Fifth Circuit, there is no further regulatory action anticipated by EPA during the remainder of the review period.

also filed a motion for expedited appeal and sought a stay of the Unilateral Orders in the interim. EPA has agreed to expedited review and to issuance of an administrative stay of the Unilateral Orders by the Fifth Circuit pending resolution of the appeal.

The TSCA statute provides Plaintiffs only limited recourse in this Court pending a decision on the SNUNs. But the agency has now rendered its decision in the form of the Unilateral Orders. The Fifth Circuit has exclusive jurisdiction to assess the validity of the Unilateral Orders and decide whether Inhance should be forced out of business permanently. Plaintiffs' and Intervenor's Motions for Summary Judgment are therefore moot.

ARGUMENT

I. The Court Should Dismiss the Complaints.

Inhance's Motions to Dismiss raise threshold legal issues, including a jurisdictional challenge to the Government's and Plaintiff-Intervenor's Complaints, that are properly before this Court. While the agency has now ruled on the SNUNs, both Complaints should be dismissed because they seek to enforce a SNUR that simply does not apply to Inhance's fluorination process.

First and foremost, as Inhance has explained, Inhance's fluorination technology is not a *new* use; it has been ongoing since 1983—over thirty years before EPA first proposed the long-chain PFAS Significant New Use Rule. And under the SNUR, any uses that predate the publication of the proposed rule in January 2015 are “ongoing” uses. 85 Fed. Reg. 45,109, 45,111 (July 27, 2020). EPA thus cannot regulate it as a “new use” under TSCA. 15 U.S.C. § 2604(a)(1)(A)(ii).

Inhance's fluorination process is exempt for another reason as well: any long-chain PFAS unintentionally generated during the fluorination process constitutes an impurity. By regulation, an impurity is a “chemical substance which is unintentionally present with another chemical

substance.” 40 C.F.R. § 720.3(m). Entities who “manufacture[] . . . or process[] the substance only as an impurity” are not subject to the rule’s notification requirements. 40 C.F.R. § 721.45(d).

Finally, the Unilateral Orders are unlawful because EPA failed to provide Inhance with fair notice that it believed the SNUR applied to the fluorination of containers until long after the SNUR was finalized—at which point the agency took the position that it was too late for Inhance to benefit from an “ongoing use” exception.

All these legal grounds (and each of them independently) are still valid and meritorious. Notably, EPA failed to address any of these issues raised in preparing and finalizing its Unilateral Orders. But this Court can and should dismiss the Complaints on the grounds that Inhance is not subject to the regulatory regime in the first place.

II. The Court Should Deny the Motions for Summary Judgment as Moot.

If the Court nonetheless proceeds to address the pending Motions for Summary Judgment, EPA’s Unilateral Orders supply another ground for denying them: Plaintiffs’ and Intervenor’s motions are moot. The Complaints argue that Inhance should be forced to submit a SNUN and that its fluorination process should be shut down pending completion of the SNUN process. *See* 15 U.S.C. § 2616(a) (describing extent of federal district court jurisdiction). Inhance, under protest, participated in the SNUN process. EPA completed that process by issuing its Unilateral Orders.

EPA’s December 1 Unilateral Orders moot the relief requested in both Complaints. ECF No. 1 ¶ 72; ECF No. 36 ¶ 110. As EPA has conceded, the Fifth Circuit now has jurisdiction over Inhance’s challenge to the Unilateral Orders. ECF No. 68 at 4; 15 U.S.C. § 2618(a)(1)(A). Inhance has filed that challenge already, and the Government has agreed to an administrative stay of the Unilateral Orders pending resolution of the Fifth Circuit appeal and to expedited briefing

and argument. In addition to inflicting irreparable harm on Inhance, if this Court were to shut down Inhance's operations now, it would interfere with the Fifth Circuit's review of the Unilateral Orders, risking inconsistent outcomes in two different federal courts.

CONCLUSION

For the foregoing reasons, Inhance requests that the Court grant its pending Motions to Dismiss and deny as moot the pending Motions for Summary Judgment.

Respectfully submitted,

/s/ Virginia Gibson
Virginia Gibson (PA Bar No. 32520)
HOGAN LOVELLS US LLP
1735 Market St., Floor 23
Philadelphia, PA 19103
Phone: (267) 675-4635
Fax: (267) 675-4601
virginia.gibson@hoganlovells.com

Catherine E. Stetson*
Susan M. Cook*
Adam Kushner*
HOGAN LOVELLS US LLP
555 Thirteenth Street, NW
Washington, D.C. 20004
Phone: (202) 637-5491
Fax: (202) 637-5910
cate.stetson@hoganlovells.com

J. Tom Boer*
HOGAN LOVELLS US LLP
4 Embarcadero Center, Suite 3500
San Francisco, CA 94111
Phone: (415) 374-2336
Fax: (415) 374-2499
tom.boer@hoganlovells.com

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Counsel for Inhance Technologies LLC